SurFACTS in Biomaterials

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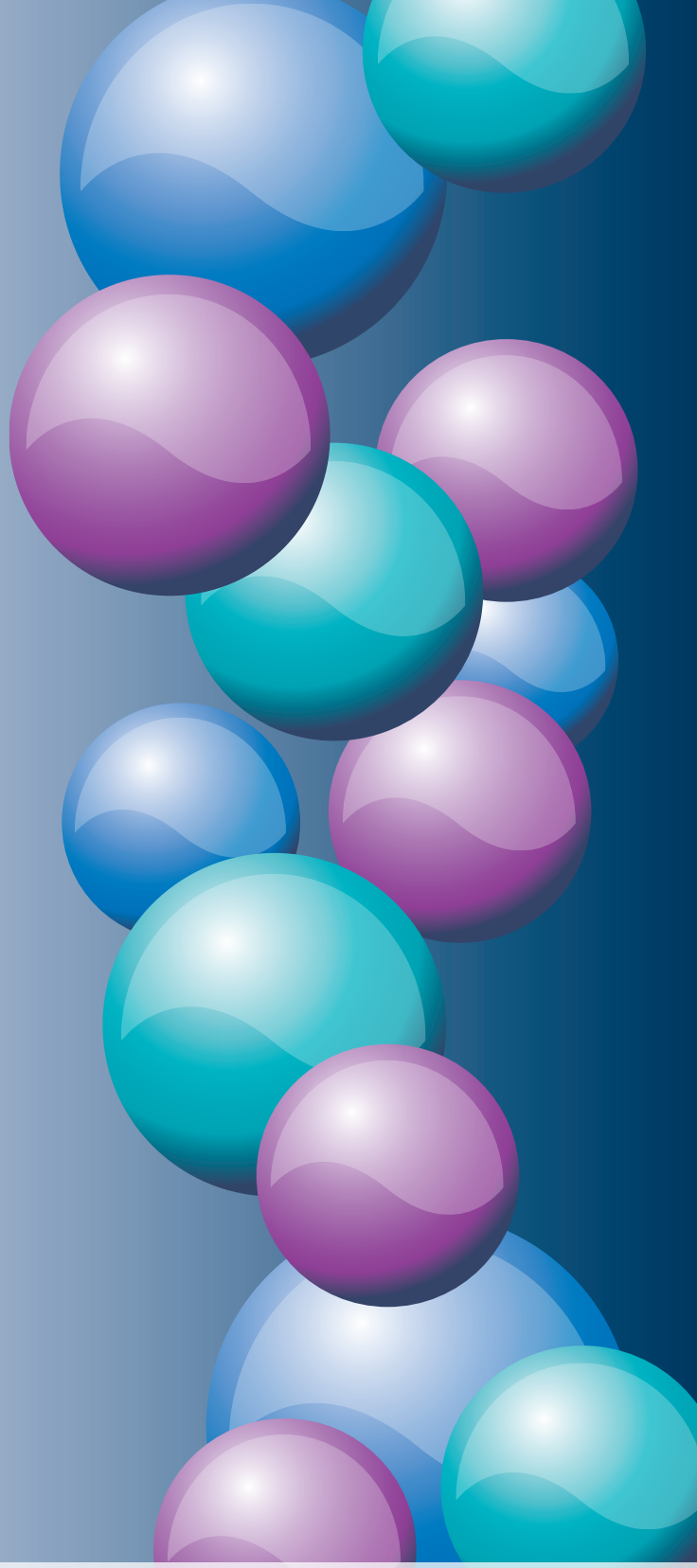

BioInterface 2008

By Carl Turnquist

A wonderful place to gather for a great meeting! These are the words that come to mind as I look forward to the Surfaces in Biomaterials Foundation's next annual workshop and technical symposium — BioInterface 2008. It will be held in downtown Minneapolis at the Millennium Hotel from Monday, October 27 through Wednesday, October 29.

This year, Monday's workshop will give special coverage to "Successful Applications of Tissue Engineering in Regenerative Medicine," led by Dave Sogard. Later in the day, we will have several Applied Technology Workshops in which companies will highlight and explain the practical uses of their technology. Following the early evening conference reception, we will hear from our conference keynote speaker, Arthur J. Coury, Ph.D., who has had a distinguished career in biomaterials at Medtronic, Focal and Genzyme. He will share his perspectives on this unique field where technology continues to mature and surprise.

Tuesday morning affords the opportunity to see the best Student Posters. Students will be at their posters to discuss their research with you. During that time, their work will be assessed by our judges for the $1,000 poster prize. At noon, the students have the opportunity to meet with industrial scientists in an informal Town Hall setting to learn more about career paths following graduation. On Tuesday morning, our technical symposium begins

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What's Inside

Regulatory Update

By Phil Triolo, Ph.D., RAC

Below are a collection of regulatory news items from various aspects of the industry:

Health Canada Requests Information on Content of DEHP and BPA in Medical Devices

Health Canada (HC), the Canadian equivalent of the US FDA, has initiated a program to determine which of the devices distributed in Canada contain DEHP (di(2-ethylhexyl)phthalate) or BPA (Bisphenol A). DEHP is commonly used to plasticize PVC; BPA is a raw material used in the manufacture of polycarbonate and some epoxy adhesives. A request to provide a list of Class II, III, and IV devices that contain more than or equal to 0.1% by mass of DEHP or are manufactured from raw materials containing or derived from BPA was formally made on Sept. 1. The latest information on the program can be found at http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_qa_im_qr_dehp_bpa-eng.php. The original HC notification can be found at http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_im_avis_dehp_bpa-eng.php.

The use of DEHP and BPA in medical devices remains a controversial issue. The US FDA assessment of the safety of the use of DEHP in medical devices can be found at http://www.fda.gov/cdrh/ost/dehp-pvc.pdf, while that of HC can be found at http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/dehp/dehp_position_draft_ebauche-eng.php . A thought-provoking article summarizing the scientific research on the health effects of BPA can be found at http://www.thegreenguide.com/doc/114/bpa.

US FDA Requires Additional Information in Premarket Notification [510(k)] Applications

If you are planning to submit a 510(k) application to the US FDA, and a clinical investigation was used to assess the safety or efficacy of your device, you'll be

Regulatory Continued on Page 16

Call for Nominations to Board of Directors, Committees

You can help make the Surfaces in Biomaterials Foundation stronger by adding your voice and opinions to the Board of Directors. The Foundation's mission is to explore creative solutions to technical challenges at the Biointerface.

The Surfaces Foundation is now accepting nominations to the Board of Directors. The positions of President-Elect, Vice President, Treasurer and Secretary will be filled at the annual meeting at the BioInterface Conference in October. Vice President, Treasurer and Secretary are one-year terms. The President-Elect effectively is a three-year term, as that person becomes President then Past President in succeeding years.

The Surfaces Foundation also is recruiting members for the Membership Committee — and for an editor and writers for SurFACTS, the newsletter of the foundation.

If you or someone you know can help move the Surfaces Foundation forward as a member of the board of directors, or through service on a committee, please forward nominations to Bill Monn at billm@surfaces.org. Deadline for nominations is Oct. 15.

SurFACTS in Biomaterials is the official publication of the foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

Senators Introduce Their Version of Anti-Preemption Bill

By Gregory de Lissovoy

Two senators have followed the lead of House lawmakers and introduced a Senate counterpart of the Medical Device Safety Act of 2008 to ensure individuals are not prevented by the Food, Drug and Cosmetic Act (FDCA) from suing devicemakers under state tort laws.

Sens. Edward Kennedy (D-Mass.) and Patrick Leahy (D-Vt.) introduced the companion bill to H.R. 6381, which has 62 co-sponsors in the House, last month.

Introduced in the House in June by Reps. Frank Pallone (D-N.J.) and Henry Waxman (D-Calif.), the bill seeks to reverse the Supreme Court's decision in Reigel v. Medtronic, which confirmed preemption of state tort suits for FDA-approved medical devices.

Following the Riegel decision, Kennedy, who chairs the Senate Health, Education, Labor and Pensions Committee, threatened to create legislation to override the court. He said Congress never intended for FDA approval to give immunity to manufacturers from liability for injuries caused by faulty devices.

"The FDA used to be the gold standard, but the agency has come under scrutiny recently. If manufacturers are putting faulty devices on the market, they must be held accountable to the patients who use them, the way Congress always intended. I will continue to fight for legislation like this that puts the health and safety of Americans ahead of manufacturers' interests," Sen. Barbara Mikulski (D-Md.), a co-sponsor of the bill, said.

The device industry warns the bill would result in more lawsuits and ultimately higher healthcare costs. "If enacted, this legislation would create a patchwork approach to medical device approvals where state courts would effectively review and regulate medical devices," AdvaMed President and CEO Stephen Ubl said.

The senators' statement can be viewed at leahy.senate.gov/press/200808/080108a.html. H.R. 6381 is available at www.house.gov/waxman/pdfs/bill_MDSA_2008.pdf.

Meeting/Conference/Trade Show Calendar

Meeting/Conference/Trade Show	Dates	Place	Web Address
3rd International Conference on Tissue Engineering	Rhodes, Greece	Sept.21-26	www.aegeanconferences.org/
Medical Design & Manufacturing (MD&M) Midwest	Chicago	Sept. 22-25	www.devicelink.com/expo/mdmmw08/
VIVA 2008 (Vascular InterVentional Advances)	Las Vegas	Sept. 23-26	www.vivapvd.com/PDFs/VIVA_2008_Brochure.pdf
2008 Biomedical Engineering Society (BMES) Annual Fall Meeting, Gateway to Innovation	St. Louis	Oct. 2-4	bme.wustl.edu/BMES2008/
American Academy of Orthopaedic Surgeons (AAOS) 2008 Fall Meeting	Dallas	Oct. 2-5	www3.aaos.org/govern/federal/nolc/nolcreg.cfm
Transcatheter Cardiovascular Therapeutics (TCT) 2008	Washington, DC	Oct. 12-17	www.tctconference.com/
American Vacuum Socitey (AVS) 55th International Symposium	Boston, MA	Oct. 19-24	www2.avs.org/symposium/
Medical Design & Manufacturing (MD&M)	Minneapolis	Oct. 21-23	www.devicelink.com/expo/minn08/
BioInterface 2008	**Minneapolis**	**Oct. 27-29**	**www.surfaces.org**
American Association of Ophthalmology (AAO)/European Society of Ophthalmology (SOE) 2008 Joint Meeting	Atlanta	Nov. 8 - 11	www.aao.org/meetings/annual_meeting/
AHA Scientific Sessions 2008	New Orleans	Nov. 8 - 12	www.americanheart.org
American Institute of Chemical Engineers (AIChE) 2008 Annual Meeting	Philadelphia	Nov. 16-21	www.aiche.org/annual

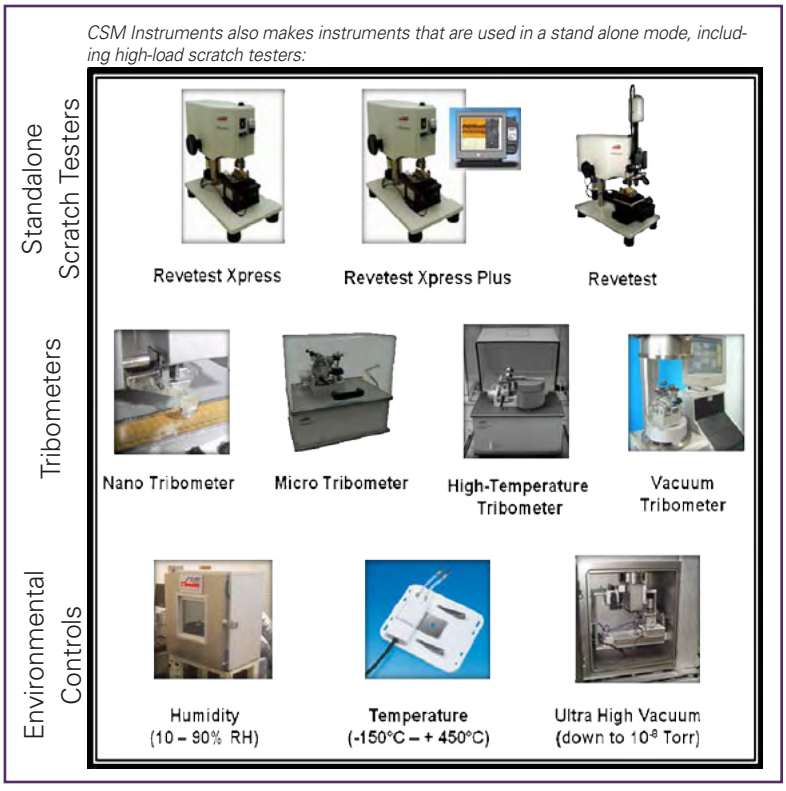
CSM Instruments

CSM Instruments has been developing state-of-the-art instruments for surface mechanical properties characterization for more than 30 years. Based on such experience we have evolved our analysis laboratory into a measurement center able to fulfill the testing and hardware requirements of our customers regarding tribology, hardness and scratch studies.

Our products include Indentation Testers, Scratch Testers and Tribometers of varying load ranges.

- Scratch Testers: Used to measure characteristics such as adhesion of a coating, delamination effects, or cracking in order to optimize coating techniques and determine failure points of the film-substrate system.
- Indentation Testers: Used to determine the hardness and elastic modulus of coatings and surfaces with extremely high precision at the macro-, micro-, and nano-scales to aid in material selection and development.
- Tribometers: Used to measure the frictional coefficient and wear rate between material pairs, as well as perform lifetime analyses.
- 3D-imaging options are available with the ConScan or AFM objective.

CSM Instruments also makes instruments that are used in a stand alone mode, including high-load scratch testers:



CSM manufactures testing modules that can be configured alone or combined together on a testing platform for a single instrument capable of multiple analysis modes. In the design of our instruments, we integrate the testing module(s) with imaging module(s) for a seamless testing and imaging process. The modules and microscopes are positionally synchronized so that the instrument automatically moves the point of interest under the appropriate imager with a single click. It also allows us to correlate optical coating failures (like cracks) to the exact force, depth, frictional force, etc. that was occurring at that time.

CSM Instruments, through collaborative efforts with a number of well-recognized industry partners, has developed extensive experience in the varied analysis methods required by the quickly evolving biomaterials field. The mechanical behavior of biomaterials (both biological and synthetic) spans multiple magni-

CSM Continued on Page 18

Lens Implant Offers Chance at Beating Lazy Eye

by Lauran Neergaard

Dr. Paul Dougherty delicately slipped a tiny lens inside the right eye of 7-year-old Megan Garvin — a last-ditch shot at saving her sight in that eye.

The California girl became one of a small number of U.S. children to try an experimental surgery to prevent virtual blindness from lazy eye diagnosed too late, or too severe, for standard treatment.

The new approach: Implantable lenses, the same kind that nearsighted adults can have inserted for crisper vision — but that aren't officially approved for use in children.

"Without this technology, we couldn't help her," says Dougherty, a prominent Los Angeles eye surgeon who invited The Associated Press to document Megan's surgery. "This would be written off as a blind eye."

Up to 5 percent of children have amblyopia, commonly called lazy eye, where one eye is so much stronger than the other that the brain learns to ignore the weaker eye. Untreated, the proper neural connections for vision don't form, eventually rendering that eye useless.

Catch it early — preferably by preschool — and it can be fairly easy to fix by patching over the strong eye, or using special drops in it, for several hours a day so that the brain is forced to use the weak eye. But the older the child is, the less effective the treatment — and by age 9, brain-eye connections are pretty well set.

The leading cause is eyes that aren't in perfect alignment. But a big difference in focusing power also triggers amblyopia. That's what happened with the Garvin girl, who had near-perfect vision in one eye but the other was too nearsighted to even see the big E on the eye chart.

It's sneaky: Kids don't realize they're seeing clearly out of only one eye, and often won't squint or otherwise signal there's a problem. So Megan was fast passing the window to correct amblyopia when a kindergarten eye exam flagged a problem.

"She reads perfectly, she's a very normal active child," says her mother, Rosie Garvin. "If she would not have had that vision test, I would never have known."

Ophthalmologists called it one of the worst cases they'd ever seen. Glasses weren't doable: One side would have required a clear lens and the other a Coke-bottle thickness, a prescription of minus 12 diopters. Her parents tried inserting a contact lens in the bad eye — getting her to roughly 20-60 vision in that eye, far from perfect but able to see blurrily while the good eye was patched.

Contacts and young kids are a tough match. Megan cried when her mother inserted it. Teachers would call to say it had popped out.

Frustrated, the Garvins ultimately opted for the implant — and days later, are feeling hopeful. It's blurry, Megan tells her mother, but she can see out of her right eye, and is chafing at the required week of rest to let the tiny incisions in her eye heal.

That's just the first step. Months of patching lie ahead to try to reverse the lazy eye, or the brain would just stick with the connections it has already formed to her strong eye. Dougherty gave no guarantees.

"I know we've got our work ahead of us," says Rosie Garvin, from Simi Valley, Calif. "I'm so relieved ... and going to make sure I do everything they tell me to make sure this works for her for life."

Implantable lenses for adults, called phakic intraocular lenses or IOLs, hit the U.S. market in 2004. Unlike cataract surgery that requires removal of the eye's natural lens because it is clouded, these lenses are put on top of a natural lens that can't focus properly, thus helping sharpen vision.

They have some risks: Surgical infection, inflammation, and a potential for cataracts to form. At about $4,000 an eye, it's more expensive than the controversial laser eye surgery LASIK, but the lenses can be removed if there are problems.

But, "how this lens is going to work in a child's eye, we don't know. We've never done studies," cautions Dr. Punin Shah, a cornea specialist at Ochsner Medical Center in New Orleans.

It is legal to implant the lenses experimentally in a child, however. A handful of medical journal reports show surgeons are starting to try the approach for hard-to-treat amblyopia. In a French study of a dozen children, all had improved vision after the surgery and half recovered normal binocular vision.

Lens Implant Continued on Page 18

Boston Center to Develop Home-Based Glucose Monitoring System

By Bernie Monegain

The Center for Connected Health, a division of Partners HealthCare, has received funding from the Microsoft HealthVault Be Well Fund to develop a home-based glucose monitoring system for patients with diabetes.

The amount of the funding was not disclosed.

Boston-based Partners HealthCare is an integrated health system that includes Brigham and Women's Hospital and Massachusetts General Hospital as well as community hospitals, health centers and a physician network.

This new initiative, Diabetes Connected Health, will use available online technology to improve diabetes management and treatment outcomes. The center will create a secure Web-based system to integrate home-based glucose monitoring results within the clinical workflow of diabetes care.

Patients from six Massachusetts General Hospital practices will use commercially available glucometers and blood pressure devices to transmit personal health data, via HealthVault, into the Partners HealthCare secure clinical systems and proprietary diabetes management application.

The system will enable patients to access personalized health information and communicate with their healthcare provider.

"We are pleased to have been selected by the HealthVault Be Well Fund to participate in advancing online solutions for both patients and providers and, specifically, to improve healthcare delivery and diabetes management," said Joseph C. Kvedar, MD, founder and director of the Center for Connected Health. "Based on our experience, we are hopeful that the Diabetes Connected Health program will increase patient and clinician satisfaction, raise patient awareness and education about their diabetes and, importantly, help improve the management of diabetes and, thereby, improve outcomes."

The Center for Connected Health is one of 15 proposed initiatives selected by Microsoft's HealthVault Be Well Fund from nearly 200 submitted.

The Microsoft HealthVault Be Well Fund is designed to stimulate not-for-profit research and development across a broad range of health disciplines that have the potential to significantly improve health and wellness. The fund helps seed innovative avenues of research and explores the potential for disruptive improvements to health management enabled by re-use and sharing of data among patients, families, caregivers, doctors and facilities.

"We're excited to help organizations like the Center for Connected Health turn their ideas into reality and to expand the capabilities and services available through HealthVault," said Peter Neupert, corporate vice president of the Health Solutions Group at Microsoft. "Our vision is to use the Internet to empower people to fully engage in managing their own health and improving health outcomes."

Nexgen Gets CE Marking for Artificial Disc

Nexgen Spine received CE Marking to market its Physio-L Lumbar artificial disc in the EU.

The device is a disc prosthesis used in the lumbar spine for patients suffering from degenerative disc disease. Its elastomeric technology enables it to mimic the mechanical properties of a natural disc, Nexgen said.

As opposed to other disc prostheses, the product helps restore the natural shock absorption of the disc, the company added.

Materials Characterization for the Bio Industry

For more than 30 years, Evans Analytical Group (EAG) has been training materials scientists/engineers in the effective use of different analytical techniques. On September 18, The company will hold its Working Smarter Course for the Bio Industry at its Sunnyvale, CA lab. Attendees will increase their knowledge of analytical methods and their understanding of how these techniques can be applied most effectively to different technologies, problem solving, or research situations.

Date: Thursday, September 18, 2008
Location: Evans Analytical Group, 810 Kifer Road, Sunnyvale, CA
For more information and to register, please visit our web site at www.eaglabs.com or contact Carrie Whitney at 408.530.3776 or email: cwhitney@eaglabs.com.

Eye on BioInterface 2008

The Surfaces in Biomaterials Foundation is proud to bestow this year's Excellence in Surface Science Award on Kenneth B. Stokes

Kenneth B. Stokes' career in the medical device field has largely been directed at controlling biomaterial surface-tissue interactions. His innovations in electronic stimulation devices provide abundant testimony to his success. In his leadership roles at Medtronic, Inc., Ken, his teams and collaborators developed the first tined and screw-in endocardial pacing leads, the first steroid eluting pacing lead tips, the first applications for thermoplastic polyurethanes and other products, largely from his ideas. His investigations into the causes of and solutions to biostability-related issues of implanted polymers constitute one of the largest bodies of such information. Some 40 patents and 150 publications amply document his record. Ken has been recognized by practitioners and organizations in his field and in the broader scientific community with honors such as: North American Society for Pacing and Electrophysiology Pioneer in Pacing & Electrophysiology, Fellow of the American Institute for Medical and Biological Engineering, and Fellow, Bakken Society. Ken is so deserving of the 2008 Excellence in Surface Science Award from the Surfaces in Biomaterials Foundation.

Keynote Speaker Art Coury Reflects on Excellence in Surfaces Science Award Winner

Certain people we know remain amazing to us for their energy and achievements. Kenneth B. Stokes, my colleague and friend for 43 years, is such a person to me. We met when I started my first job at General Mills Chemicals, Inc. in 1965. Ken was an experienced polymer scientist, and I was a rookie organic chemist trying to learn polymers. We overlapped and collaborated there for some five years, and, when he left for Medtronic in 1970, I inherited all of his projects. We came together in 1976 when I joined Medtronic. By then, he had established himself as their premier polymer scientist and Director of Leads Research and Engineering. New technologies emanating from his ideas, teams and collaborators include the first tined and screw-in endocardial lead devices, the first implant use of thermoplastic polyurethanes and the first steroid-eluting pacemaker lead tips, among others.

Some 40 patents and 150 publications amply document these innovations. The fact that they survive to this day assure his legacy. Ken and I collaborated for 17 years at Medtronic, studying, in particular, biostability issues in biomaterials which generated one of the largest sources of information in the field. Whether Ken served as a blocking back for our touch football team or head of the pacing lead team, his dedication and drive assured success.

FDA Proposes Program To Boost Orthopedic Device Safety

FDA wants to create a program that would search public and private databases to help determine the efficacy of orthopedic implants, Government Health IT reports.

The program is part of a larger effort, called the Sentinel Initiative, launched by FDA earlier this year to monitor and provide early warnings of potential problems associated with FDA-approved medical products.

The implant program would create a distributed network to let the department search multiple data sources for information about medical products. Officials hope to be able to search government databases, such as the Medicare database, private and public medical claims databases, and electronic health record systems, according to an FDA spokesperson.

FDA's current post-market surveillance programs require "health care professionals and patients to first recognize an association between an adverse effect and a medical product, and then report it to FDA," the spokesperson said.

In September, FDA will issue a request for quotations to find companies that could evaluate orthopedic implant databases for inclusion in the program.

FDA Gives 510(k) Clearance to LTC's VAD System

Live Tissue Connect (LTC), a subsidiary of CSMG Technologies, received 510(k) clearance from the FDA to market its LTC VAD System.

As opposed to conventional surgical closing devices such as sutures or clamps, the VAD.400 generator and two disposable instruments are used in open surgical and gynecological procedures to bond and reconnect human soft tissue through fusion, CSMG said.

The system can be used on veins and arteries up to 7 mm in diameter, on ducts up to 2 mm in diameter and tissue bundles that can fit in the jaw electrodes of the instruments.

MEMBER SPOTLIGHT

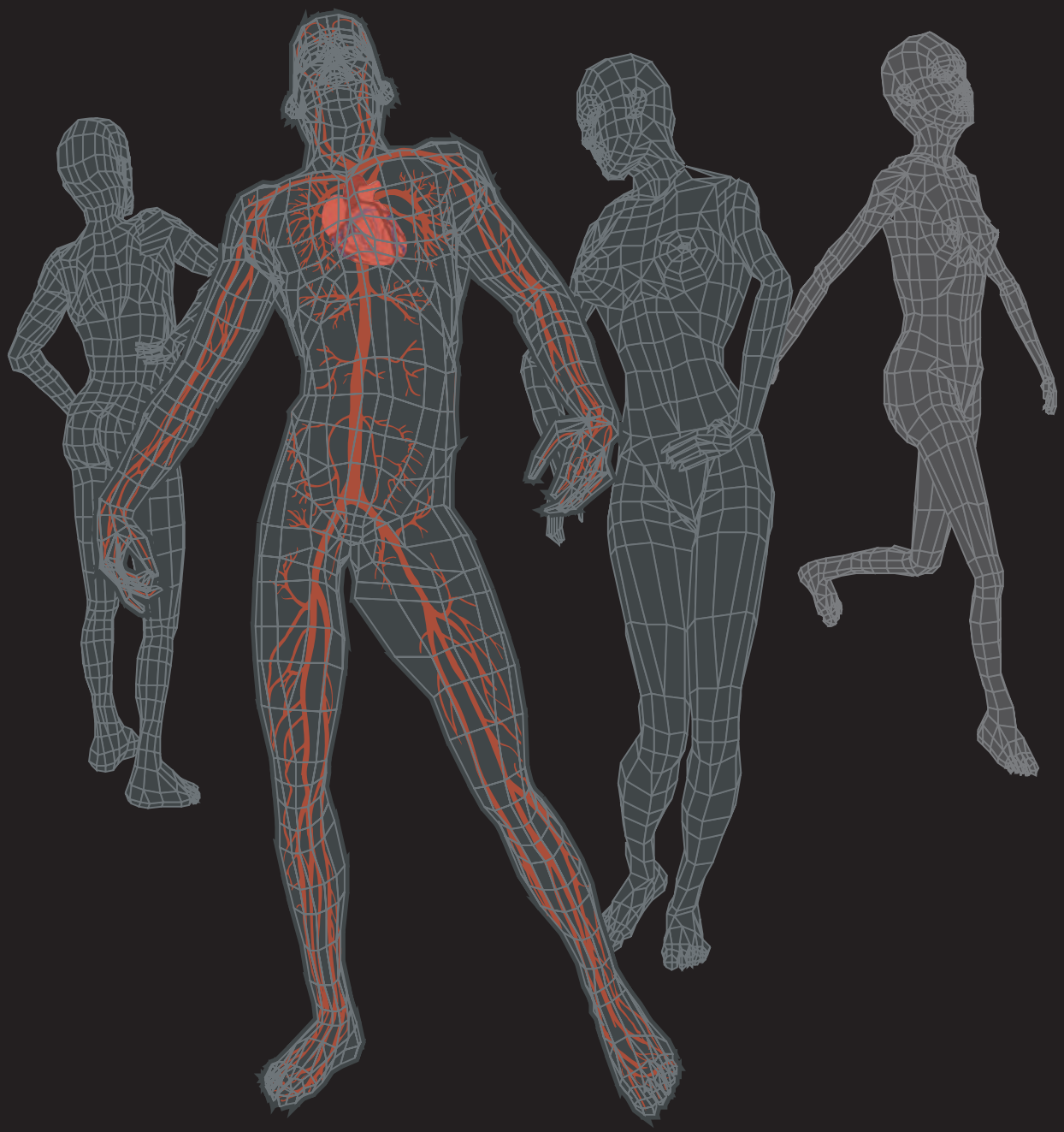
Q-Sense

Q-Sense is a Swedish-based company specializing in quantifying changes at various interfaces. Q-sense provides researchers & developers in the academic & industrial sectors with analytical instruments & complete measurement solutions for molecular interaction & adsorption based on the unique & patented Quartz Crystal Microbalance with Dissipation Monitoring (QCM-D) technology. Their products are mainly used for the analysis of biomaterials and biological interfaces.

What makes QCM-D different is that it can measure the change in frequency and the rate of energy dissipation (ΔD) or loss. The rate of dissipation is related to the viscoelastic or structural properties of the material. By measuring both the dissipation (D) factor and the frequency (f), it is possible to analyze the whole chain of reactions that occur when a new substance is introduced to a specific surface.

By delivering world-class information and innovative tools to researchers, students, educators and practitioners worldwide, Q-Sense helps to increase productivity as well as effectiveness. With continuous enhancements to their products and their focus on providing outstanding support and service to their customers, Q-Sense continues to increase their presence across the globe.

Q-Sense instruments are found in over 25 countries world-wide and there are currently over 350 publications citing the use of the QCM-D technology. Q-Sense is headquartered in Gothenburg, Sweden with a subsidiary sales office in Glen Burnie, Maryland. Q-Sense is proud to be a sponsor of Biointerface 2008! We look forward to meeting you at the upcoming workshop and symposium on October 27!



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W. L. Gore & Associates Announces Positive Interim Study Results for Gore Propaten® Vascular Graft and Gore Viabahn® Endoprosthesis With Heparin Bioactive Surface

W. L. Gore & Associates (Gore) recently announced encouraging interim results and a pivotal study update from several ongoing prospective studies for its peripheral vascular products, including the Gore Propaten® Vascular Graft and Gore Viabahn®® Endoprosthesis. The data was recently presented to clinical audiences at the 2008 Annual Meeting for the Society of Vascular Surgery (SVS) in San Diego, California.

The ongoing Gore Propaten® Vascular Graft studies report primary patency rates as high as 79 percent at one year for below-knee bypasses. Prior to the Gore Propaten® Vascular Graft being available, non-heparin-bonded synthetic grafts achieved an average primary patency rate of 66 percent in below-knee bypasses at one year. Several study updates provided support for the Gore Propaten® Vascular Graft as the synthetic graft of choice in lower-limb and dialysis access applications. These include:

- Richard Neville, MD, reported on an ongoing study at Georgetown University Medical Center, Washington, D.C. Sixty-two below-knee bypasses were implanted for critical limb ischemia (29 percent rest pain and 71 percent ulceration/gangrene) of which 77 percent were to tibial arteries and the remaining 23 percent were bypasses to the below-knee popliteal artery. The primary patency at one, six, and twelve months for below-knee bypasses was 92 percent, 88.5 percent and 79 percent respectively by life table analysis.

- Michael Stoner, MD, East Carolina University, Greenville, N.C., also reported on implants for above-knee and below-knee bypasses. Thirty-three above-knee and 12 below-knee Gore Propaten® Vascular Grafts were implanted since February 2007. The majority of the below-knee implants (83 percent) had a Rutherford classification of either four or five, were tobacco users (92 percent), had poor run-off (less than two) (83 percent) and 50 percent were diabetic. The one year primary patency for the below-knee bypasses were reported to be 79 percent.

  The majority of the above-knee implants (97 percent) had a Rutherford classification of three, four or five, were tobacco users (64 percent) and had poor run-off (less than two) (64 percent). The one year primary patency for the above-knee bypasses was reported to be 87 percent. The above-knee Gore Propaten® Vascular Graft implants were then compared to 169 historical implants of non-heparin-bonded grafts at the same institution and were found to have a trend toward improved primary assisted patency for patients with poor run-off.

- William Jordan, MD, University of Alabama, Birmingham reported on 44 implants (38 lower extremity [Ten below-knee]), two upper extremity, three visceral revascularization and one carotid). Thirty-nine of the 44 implants were patent at last follow-up up to one year, giving a gross patency of 89 percent.

- Ingemar Davidson, MD, PhD, FACS, at University of Texas, Southwestern Medical Center in Dallas, Texas, presented interim results of a prospective, non-randomized study comparing Gore Propaten® Vascular Graft to a non-heparin-bonded graft in difficult patients for hemodialysis access application. Sixty Gore Propaten® Vascular Grafts were compared to 59 non-heparin-bonded grafts implanted since January 2007. The Gore Propaten® Vascular Graft was generally preferred for difficult, high-risk patients. At six months, the Gore Propaten® Vascular Grafts were found to have significant improvement of 20 to 25 percent in the clot-free and graft survival time as compared to the control group.

"We are extremely pleased to see the positive study results of the Gore Propaten® Vascular Graft in lower limb and dialysis access applications," said Deenu Kanjickal, PhD, Product Specialist for the Gore Propaten® Vascular Graft. "More than 15,000 Gore Propaten® Vascular Grafts have been successfully implanted worldwide since commercial availability."

The Gore Propaten® Vascular Graft is the first and only vascular graft of its kind on the market approved for the treatment of Peripheral Arterial Disease (PAD) in the lower extremities. This unique surgical graft is designed to address the gap in clinical performance between synthetic and vein grafts by bonding the anticoagulant drug heparin to the surface of the graft, with the potential to reduce thrombosis or clotting.

Additionally, Gore is pleased to release details of an interim report about the Gore Viabahn® Endoprosthesis from a study for the management of superficial femoral artery oc-

Gore Continued on Page 18

Wanted: Members

To be leaders in the surface science community

- Join a forum that fosters discussion and sharing of surface and interfacial information
- Have your voice heard and your interests represented within the surface science and biomedical community
- Help shape workshops and symposia that further the world-wide education of surface science
- Promote understanding of interfacial issues common to researchers, bio-medical engineers and material scientists.

Benefits of Membership:

- Discounted registration at BioInterface, the annual symposium of the Surfaces in Biomaterials Foundation.
- Your logo and a link to your Web site in the member directory on the official Web site of the Foundation, www.surfaces.org.
- Complimentary full page ad in surFACTS, the Foundation's newsletter and discounts on all advertising.

Join the Foundation that connects the academic, industrial, and regulatory committees within the surface science/biomedical communities!

Visit the Foundation at www.surfaces.org for a membership application or call 651-290-6267.

Surfaces in *Biomaterials* Foundation

Pressure-Sensing Contact Lenses

A tiny electrical circuit built into contact lenses may provide 24-hour monitoring for glaucoma.

By Jennifer Chu

Currently, the only way for patients with glaucoma to keep tabs on the disease is to go to the doctor's office. There, a clinician administers one of several tests to measure glaucoma's main risk factor, intraocular pressure (IOP), and prescribes medication accordingly. But such visits normally occur two or three times a year, and there's no take-home monitoring device for patients who may experience pressure spikes between visits.

Now scientists at the University of California, Davis, have designed a contact-lens prototype with a built-in pressure sensor, using a novel process that etches tiny electrical circuits within a soft polymer material. The lens's designer, Tingrui Pan, assistant professor of biomedical engineering, says that the design may eventually be fashioned into disposable contact lenses, enabling patients to continuously monitor glaucoma at home.

In glaucoma, drainage of the fluid that normally delivers nutrients to and removes metabolic waste from the eye is blocked. Elevated pressure in the eye ultimately presses on the retina, compromising neural activity and damaging the optic nerve, resulting in loss of vision. Doctors manage glaucoma by measuring patients' IOP and prescribing drugs to lower it.

"It's very different from situations like cardiac disease or diabetes, where patients can wear devices that measure heart rate or blood pressure 24 hours a day for a week or more to get a better idea of what's going on," says James Brandt, a professor of ophthalmology at UC Davis and Pan's collaborator. "We don't have that for glaucoma, and that's one of the biggest clinical frustrations we have."

Pan's team recently made a contact-lens prototype from PDMS, an organic polymer commonly used to make contact lenses and breast implants. "This material has been widely used in biology because it's easy to work with and can bend and flex like skin," says Pan. "But the problem is, it's not conductive, and if you want to make it sensing, it has to be conductive."

Because it's difficult to adhere metal wires directly to the polymer's surface, Pan looked for ways to embed metal within the polymer. He first made the polymer sensitive to ultraviolet (UV) light by mixing it with a chemical agent. When exposed to UV light, the polymer solidifies, forming a soft, rubberlike material. Without UV light, the polymer remains in its liquid form.

The team then created a negative cutout in the pattern of a small circuit and shined UV light through the cutout, onto a layer of polymer mixture. Areas exposed to light gelled, while those under the cutout did not. Researchers were able to easily wash away the liquid polymer, leaving an imprint of a small, nanoscale circuit within the solidified polymer.

Pan filled the pattern with a solution of powdered silver, a nontoxic metal conductor. After polymerization, the silver formed a continuous circuit within the soft polymer. In initial laboratory tests, the team found that voltage within the tiny circuit changes slightly as the polymer is bent. Pan says that measuring this change could provide a good monitor for IOP: as pressure within the eye increases, the shape of the contact lens would distort, causing a change in voltage within the wires. The researchers published their results in a recent issue of the journal *Advanced Functional Materials*.

"This device is really a breakthrough in real-time IOP monitoring," says David Calkins, associate professor of ophthalmology at Vanderbilt University Medical Center, who was not involved in the research. "We don't have a means right now to measure pressure in real time outside of the clinic. Because of that, we are missing the fluctuations in IOP that could be pertinent to the pathogenesis of glaucoma."

However, several hurdles remain before the prototype can be fashioned into a practical contact lens. In the current version, the silver circuit is opaque and would obviously obstruct vision. Pan says that such a visible circuit could still be used for short-term, sit-down tests in the clinic. However, he is also looking for materials that may be made into transparent circuits for longer-term use.

Powering the lens also presents a problem. Ideally, Brandt says, a "smart" contact lens would consist of an electrical pressure sensor as well as an RFID tag to wirelessly transmit information to a computer, along with a small battery to power the device. "Getting energy to the device, and pulling information off of it, is not a trivial task," he says.

BioInterface 2008

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[1]Students who submit a Technical Poster are given free registration to the Symposium (Technical Symposium only; not the workshop)

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Regulatory Continued from Page 2

required to include information on the clinical trial. "If your 510(k) includes data from a clinical trial, you must determine if your study is applicable for entry into the clinical trial registry data bank at ClinicalTrials.gov. An applicable device clinical trial is a prospective clinical study of health outcomes comparing an intervention with a device against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes). (See http://www.fda.gov/CDRH/DEVADVICE/314b.html and Title VIII - Clinical Trial Databases.) Information on how to register your clinical trial(s) in the ClinicalTrials.gov data bank is available on the National Library of Medicine (NLM) Protocol Registration System (PRS) website.

Note that 510(k)s that "contain no clinical data" are not required to include form 3674, which can be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674_508.pdf.

Additionally, if your 510(k) includes a certification to conformance with a standard, you'll need to include form 3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf with your submission. The form takes a while to fill out as it requires that each section of the standard be identified along with an indication whether conformance with each section is met and justification for any determination that the section is not applicable.

Patent Rule Changes Rejected by Court

A rule issued by the U.S. Patent and Trademark Office (PTO) limiting the number of Continuations in Part that could be filed with a U.S. Patent Application was recently struck down in court. The PTO exceeded its authority when it issued its rules in August 2007 and altered the way patent applications are reviewed, according to U.S. District Judge James Cacheris. The rule had required that, beginning Nov. 1, 2007, each parent application would be limited to a maximum of three continuing applications — two continuation or continuation-in-part applications, and one request for continued examination — without justification. The change in rules was prompted by an increase in the number of Continuations received by the PTO http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aqCAFWKjF1Ns . The ruling is a victory for the medical device and pharmaceutical industries which had argued strongly against the limitations http://www.advamed.org/NR/rdonlyres/45841817-4F59-4154-A79C-48B2ECCC0593/0/AdvaMedIPWGViewsOnPatentReformAct.pdf.

Medtronic Endeavor and Abbott Xience Drug-Eluting Stents (DES) Approved by FDA; New Study Supports Safe Use of DES

The FDA approved U.S. marketing of Medtronic's Endeavor's Zotarolimus-Eluting and Abbott's XIENCE™ V Everolimus-Eluting Coronary Stents on February 1 and July 2, 2008, respectively. A summary of the safety and effectiveness information for Endeavor is posted at http://www.fda.gov/cdrh/pdf6/p060033b.pdf; Summary data for Xience will be posted at http://www.fda.gov/cdrh/pdf7/p070015.html. According to a preliminary analysis of the clinical trial data supporting the safety and efficacy of the Xience DES, http://www.bloomberg.com/apps/news?pid=20601103&sid=a0rTbGr23Bhg&refer=news, Abbott's device may offer some advantages over existing drug eluting stents.

Also, there is good news for drug-eluting stent manufacturers. A recent study comparing outcomes of Medicare beneficiaries who underwent nonemergent coronary stenting before and after the availability of drug-eluting stents concluded that "The widespread adoption of drug-eluting stents into routine practice was associated with a decline in the need for repeat revascularization procedures and had similar 2-year risks for death or ST-elevation myocardial infarction to bare-metal stents." Results, published in the June 25 edition of the *Journal of the American Medical Association* (JAMA. 2008 Jun 25;299(24):2868-76) were based on claims data of 38,917 Medicare patients who underwent nonemergent coronary stenting from October 2002 through March 2003 when only bare-metal stents were available (bare-metal stent era cohort) and 28,086 similar patients who underwent coronary stenting from September through December 2003, when 61.5% of patients received J and J's Cypher drug-eluting stent and 38.5% received a bare-metal stent (drug-eluting stent era cohort). The use of DES, which decreased by approximately 40% in 2007 after 2006 reports indicating that DES could trigger late-stage thrombosis, has rebounded considerably in 2008.

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with initial sessions on "NanoBioTechnology," led by William Lee of AST Products and "Surface Characterization," led by Nicholas Randall of CSM Instruments.

After lunch, we will conduct our brief annual business meeting for the Surfaces in Biomaterials Foundation. This meeting will provide a good opportunity for you to voice your topic ideas and suggestions for the BioInterface 2009 workshop and symposium. Please plan to attend!

Tuesday afternoon's first session is "Orthopedic Implants and Devices" led by Shrojal Desai of BSCI. Then Joe Chinn moderates the popular "Point-Counterpoint" debate session on the topic "Nanoengineering: Enabling Technology or Marketing Slogan?"

Wednesday morning begins with the "Drug Eluting Medical Devices" session chaired by Yen-Lane Chen of Boston Scientific. This is followed by "Hospital Acquired Infections and the CMS: The Coming Wave of Anti-Infective Medical Devices," led by Larry Salvati of DePuy. Following the luncheon, the "Excellence in Surface Science Award" will be given to Ken Stokes and he will give his award address to conferees.

On Wednesday afternoon, we offer a unique technical session, entitled "Cell Communicating Surfaces," chaired by Aylvin Dias of DSM/PTG. The afternoon will be completed by an "Antimicrobial Technology Solutions" poster session in which several companies will make 5 minute presentations on their specific antimicrobial technology.

All in all, an enlightening three days together where folks from industry can meet and greet their colleagues from academia. In addition, we will have exhibitors on hand to demonstrate and discuss their technical offerings with conferees. The setting is in downtown Minneapolis during the mild October weather there. Please plan to attend. Registration information is available at www.surfaces.org. I look forward to seeing you there!

CSM Continued from Page 4

tude levels, from the intracellular forces operating at the molecular level to macroscopic organization of multi-layer coating systems commonly employed. Using the combinatorial methods available through CSM Instruments, taking mechanical analysis beyond the traditional realm is now possible for the industrial and educational researcher.

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CSM Instruments is proud to announce the launch of its new Table Top Nano Indentation Tester (TTX), a cost-effective solution which meets the ISO 14577 & ASTM E2546 standards.

Lens Implant Continued from Page 5

Other surgeons are experimenting with LASIK in children like Megan, although she wasn't a LASIK candidate — her corneas were too thin for it to be done safely, and Dougherty says it doesn't work well for such severe nearsightedness.

Dr. Michael Repka, a pediatric ophthalmologist at Baltimore's Johns Hopkins University, says both approaches are in their infancy, but interesting.

"It's an exciting thing in a patient who has had conventional therapy and failed," says Repka, a spokesman for the American Academy of Ophthalmology.

And while catching lazy eye very young is best, stay tuned: Repka's own research shows it can be possible to treat after age 9, long the cut-off, and he is to publish details soon.

Gore Continued from Page 11

clusive disease. Karen McQuade, MD, of Baylor University Medical Center in Dallas, Texas, reported comparable 24-month patency rates between surgical above-knee femoropopliteal bypass and endoluminal bypass.

So far in the study of 100 treated limbs, the stent-graft group is showing primary patency of 82 percent, 73 percent, and 62 percent for six months, one year, and two years, respectively. For the same respective time points, primary patency for the surgical group, comprised of non-heparin-bonded, mostly polyester grafts, was 88 percent, 79 percent, and 65 percent. Similar secondary patency rates were seen at six months, one year, and two years (86 percent, 84 percent, and 73 percent, respectively, for stent-grafts versus 90 percent, 83 percent, and 75 percent, respectively, for the surgical grafts). According to Dr. McQuade, the interim results of this study may support the use of stent-grafts as an alternative to surgery in the management of superficial femoral artery occlusive disease.

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